

REMARKS

Claims 5 and 6 are pending.

Rejection Under 35 U.S.C. §103(a) Over Arora et al. (United States Patent No. 5,637,570) in view of Bouveng (Acta. Chem. Scand., 1961, 15, pp 96-100)

Claims 5 and 6 have been rejected as obvious over Arora et al in view of Bouveng.

Applicants respectfully traverse the rejection for the following reasons.

The Examiner's position is that processes disclosed in Arora et al. in combination with the disclosure of Bouveng, makes applicants' instant claims obvious. As an initial matter, it is clear that Arora et al. differs from the instant claims, in that the disclosure of Arora et al. is directed to compounds wherein the sugar is not substituted with a carbamate moiety.

Further, there is no teaching or suggestion in Arora et al. to employ processes to create a carbamate group at the 4-position of the compound of Formula I. The disclosure of Arora et al. shows that R<sub>2</sub> in the -OR<sub>2</sub> group can take the values of hydrogen, C<sub>10</sub>-C<sub>15</sub> alkyl, -(CH<sub>2</sub>)<sub>n3</sub>-N-[cyclic alkyl group optionally containing an oxygen atom] or -(CH<sub>2</sub>)<sub>n5</sub>-N(CH<sub>3</sub>)<sub>2</sub>, wherein n<sub>3</sub> and n<sub>5</sub> can be 2-6 and 2-4 respectively.

The Examiner asserts that "[i]t would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the process for conversion of the 4-hydroxy group to its corresponding nitrogen containing heterocyclic moiety of Arora in view of the teachings of Bouveng to a process of conversion of a free hydroxyl group to its corresponding carbamate by treating with an isocyanate reagent because Arora discloses that the said compounds exhibit greater potency for cancer treatment and provides ease of oral administration when the 4-OH is substituted with a nitrogen containing heterocyclic moiety." (pages 3-4, Final Action).

Applicants strongly and respectfully disagree with the quoted statement to the extent that the Examiner is suggesting that Arora et al. discloses applicants' claimed processes for making the particular compounds, suggests applicants' claimed processes for making the particular compounds, or contains any disclosure or suggestion of the usefulness of applicant's claimed processes for making the particular compounds.

The Examiner states that "one skilled in the art would have a reasonable expectation for success in combining the teachings of Arora et al. and Bouveng references to accomplish the compounds of 2,3-O-isopropylidene- $\alpha$ -L-xylo-2-hexulofuranosonic acid of Formula I (Arora et al.) wherein sugar is substituted with a carbamate group (Bouveng)."

In fact, Arora et al. contains no suggestion or motivation for modification of the compounds of Formula I at the 4-position of the structure whatsoever. The exact language of Arora et al. is actually the following: "It appears that L-hexoses coupled with substitution at the 1-position (preferably alkyl) and another substitution at 5- and/or 6-position (preferably o-heterocyclic alkyl, heterocyclic alkyl, N-heterocycle, N-heterocyclic alkyl, etc.) plays an important role for displaying significant activity..." (col. 2, lines 38-43; emphasis added). Thus, there is no mention at all of the 4-position, much less a suggestion to modify or substitute the Arora et al. compounds at the 4-position, and even further removed from any hint that the 4-position of Arora et al. compounds should or might be substituted with a carbamate.

To remedy this deficiency, the Examiner attempts to combine Arora et al. with Bouveng. This latter publication appears to disclose the investigation of the distribution of O-acetyl groups in glucuronoxylan from birch wood using phenylcarbamoyl groups as protective substituents (see Abstract).

It does not appear that the cited reference is at all relevant to the obviousness (*vel non*) of the claimed processes. There does not appear to be any disclosure or suggestion of the processes to make 2,3-O-isopropylidene- $\alpha$ -L-xylo-2-hexulofuranose compounds. The teaching of the reference, namely that a 4-hydroxyl group can be transformed to a phenylcarbamoyl group in a carbohydrate of no relevance to applicants' claimed compounds, does not constitute a *prima facie* case of obviousness in the present case.

Furthermore, there appears to be no pharmaceutical application to the Bouveng reference in the slightest. It is inconceivable that one of ordinary skill in the art, considering processes to make the compounds disclosed in Arora et al., would look to the disclosure of Bouveng to arrive at a process to create a 4-carbamate hexulofuranose with any expectation whatsoever that such a compound could have any utility as a pharmaceutical agent.

There is no suggestion or motivation contained in the Bouveng reference to arrive at applicants claimed processes. Again, absent such suggestion or motivation, the Examiner's position that it would have to obvious to combine Arora et al. with Bouveng is pure and impermissible hindsight. Applicants respectfully request that the rejection be reconsidered and withdrawn.

#### CONCLUSION

Applicants submit that the claims are allowable as written, and respectfully request a Notice of Allowance as the next mailing from the Office.

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Applicants enclose herewith a Petition for Extension of Time to respond to the Office Action from January 21, 2005 to April 6, 2005. The Petition includes an authorization to charge the required fee. A Notice of Appeal is also submitted herewith. Authorization is hereby given to charge any fees deemed to be due in connection with this Action to Deposit Account No. 50-0912.

Respectfully submitted,

ARORA *et al.*

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Date: April 6, 2005

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